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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,281	07/06/2000	Clive M. Elson	CGR-013CP2	5564

959 7590 06/19/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/610,281	Applicant(s) Elson et al.	
	Examiner L. E. Crane	Group Art Unit 1623	

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

- ☒ Responsive to communication(s) filed on **-10/20/02 (amdt A) & 10/24/02 (IDS)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claims **---1-26---** are pending in the application. Claim **-1-** have been cancelled.
Of the above claim(s) **---1---** is/are withdrawn from consideration.
- ☐ Claim(s) **---1---** is/are allowed.
- ☒ Claims **---1-26---** are rejected.
- ☐ Claim(s) **---1---** is/are objected to.
- ☐ Claim(s) **---1---** are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-1-** is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-1-** is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-1-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: **-1-**.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--05--**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-1-**

U.S. Patent Trademark Office

Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 09/610,281

Copy for ☒ FILE ☐ APPLICANT

Paper No. **06**

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No claims have been cancelled, claim 26 has been amended, and no new claims have been added as per the preliminary amendments filed October 20, 2002. An Information Disclosure Statement (IDS) filed **October 24, 2002** has been received with all cited references and made of record.

Claims 1-26 remain in the case.

Incorporation by reference of essential material by reference to a foreign application or a foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by applicant, or a practitioner representing applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to any other reference including US patents is improper because applicant has not provided the proper direction concerning which particular part or parts thereof is/are to be incorporated and provided the appropriate declaration therewith. See the disclosure at page 4-5, bridging sentence; and page 6, at lines 18-19. Deletion of all such incorporations by reference is respectfully requested.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

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Claims 6 and 7 are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See
5 for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. ,1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966). See claims 6 and 7 for the term "used." Examiner suggests substitution of the noted term with the term -- administration -- or the like.

10 Claims 15 and 24 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 In claim 15 the term "serous cavity" is not defined in Taber's Cyclopedic Medical Dictionary nor is said term indexed in the Merck Manual (17th Ed.). Examiner respectfully requests a medically accepted definition of this term. Did applicant intend to refer to -- a lymph node --?

20 In claim 24 the term "tissue adhered together comprises a defect in said tissue" is unclear or ambiguous. This term appears to read on surgical adhesions. Clarification is respectfully requested.

25 The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ

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619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

5 A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

10 Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

15 Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 1-4 of copending Application No. 09/315,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because the now allowed method directed to tissue-adherent NOCC-coated solid supports to prevent attachment of *ex vivo* cell-products appears to overlap with the instant claimed drug delivery devise.

20 This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

25 "A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 18-26 are rejected under 35 U.S.C. §102(b) as being anticipated by **Higham et al. '319** (PTO-1449 ref. A10).

10 **Higham et al. '319** discloses the utility of N, O-dicarboxymethyl-chitosans (NOCC) based films in the prevention of adhesion between tissues brought into contact following injury and/or surgical intervention/incision, see column 2, lines 19-32.

Claims 18-26 are rejected under 35 U.S.C. §102(b) as being anticipated by **Prodex, Inc. '022** (PTO-1449 ref. A17).

15 **Prodex, Inc. '022** discloses covalent cross-linking of NOCC with a variety of different dialdehydes listed at p. 3, lines 10-11. The '022 reference also discloses at page 2, lines 52-55, that these compositions may be used to prevent undesirable tissue adhesion by appropriate administration during or following surgery.

20 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 is (703) 308-4556.

25 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can

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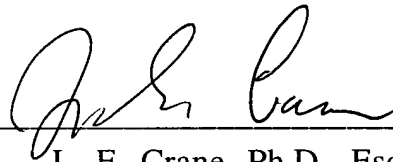
normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-
5 308-4624.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec

10 06/16/03



L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600